

CERTIFIED FOR PUBLICATION

IN THE COURT OF APPEAL OF THE STATE OF CALIFORNIA

SIXTH APPELLATE DISTRICT

F. HOFFMAN-LA ROCHE et al.,

Petitioners,

v.

THE SUPERIOR COURT OF  
SANTA CLARA COUNTY,

Respondent;

BARRY WERTHEIMER et al.,

Real Parties in Interest.

No. H027794

(Santa Clara County  
Super.Ct.No. CV006507)

When Steven Wertheimer was 14 years old, he committed suicide by throwing himself in front of an oncoming Caltrain after undergoing a six-month course of Accutane—a drug prescribed for the treatment of cystic acne. In a products liability survivor action that followed, Steven’s parents, Barry and Laurie Marks Wertheimer, alleged that side effects of Accutane include depression, psychosis, and suicidality, and that these effects had caused Steven’s death.<sup>1</sup> Wertheimers named six “Roche Group” pharmaceutical companies as defendants in the action, including Swiss defendants Roche Holding Ltd. (Roche Holding) and

---

<sup>1</sup> For ease of reference and meaning no disrespect, we will collectively refer to Barry and Laurie Marks Wertheimer, the plaintiffs and real parties in interest in this proceeding, as “Wertheimers.”

F. Hoffman-La Roche Ltd. (F. Hoffman), and two U.S. Roche companies that are domiciled in New Jersey.

In this statutory writ proceeding, the Swiss defendants challenge the trial court's exercise of in personam jurisdiction over them. They contend that because Roche Holding is simply a passive, parent holding company that invests in pharmaceutical companies, and because F. Hoffman only sells the active ingredient in Accutane in Switzerland to the domestic U.S. Roche affiliates that manufacture and sell the drug here, the trial court's exercise of jurisdiction over them was error. Wertheimers retort that the U.S. Roche defendants are agents of the Swiss defendants, and that jurisdiction over the Swiss defendants is proper not through these companies' own direct contacts with California, but by application of the "representative services" doctrine—a species of agency that permits a court to exercise general jurisdiction over a foreign defendant where that entity is the principal of a related domestic entity that functions merely as its instrumentality or agent.

On the factual record here, we hold that the trial court's exercise of jurisdiction over either of the Swiss defendants based solely on the global exchange and management of medical and scientific information relative to drug safety and regulatory compliance offends constitutional due process considerations. We accordingly let a writ of mandate issue directing the trial court to vacate its order of July 15, 2004, denying a motion to quash service of summons and enter a new order granting the motion as to each Swiss defendant.

#### *Summary of Proceedings Below*

The operative complaint alleges that Steven Wertheimer was a "popular, healthy, happy, well-adjusted 14-year[-]old teenager with no prior history or symptoms of mental health problems" when he "spontaneously took his own life by thrusting himself in front of a speeding Caltrain train in Palo Alto." Some four months before that tragic act, Steven had completed a prescribed six-month course of Accutane, the common name for the prescription acne drug, Isotretinoin. The drug is alleged to be manufactured and sold by "Hoffman-La Roche, Inc.; Roche Laboratories, Inc. ["The U.S. Roche defendants"]; F. Hoffman-La Roche

Ltd.; Roche Holding AG; F. Hoffman La-Roche AG; and Roche Holding, Ltd., hereinafter ('La Roche')."<sup>2</sup>

The causes of action pleaded against the four defendants subsumed by Wertheimers within the group label "La Roche" are breach of express warranty, breach of implied warranty, strict products liability (failure to warn), negligence, fraud and deceit, and negligent misrepresentation, all relating to Accutane. Allegations common to each cause of action include that in June 1982, the United States Food and Drug Administration (FDA) approved the use of Accutane for cases of severe cystic acne, and that defendants knew even then that high doses of it "cause sudden onslaughts of psychosis, depression, and suicidality." The Roche defendants are alleged to have "downplayed the risk of sudden incidents of suicide" and to have "repeatedly denied that the ingestion of Accutane has any causal link to suicide."

All defendants are alleged to be the agents of one another, and Roche Holding is specifically alleged to be "a joint-stock company with its registered office in Basel, Switzerland, whose purpose is to hold shares in companies that manufacture pharmaceutical and other products." Roche Holding is further alleged to be the parent company of F. Hoffman, which is likewise located in Basel, as well as of the two U.S. Roche defendants, both of which are alleged to be New Jersey corporations and "wholly owned subsidiaries." Through these allegations, Wertheimers themselves cast Roche Holding as a mere parent holding company.

On their motion to quash in the trial court, the Swiss defendants proved up these holding company allegations by offering uncontroverted evidence that the two U.S. Roche defendants are, ultimately, wholly owned subsidiaries of Roche Holding.<sup>3</sup> They also established without

---

<sup>2</sup> This writ proceeding does not involve named defendants Roche Holding AG or F. Hoffman La-Roche AG. Nor does it involve other named medical provider defendants.

<sup>3</sup> According to that evidence, Roche Holding owns shares in Roche Finance, Ltd., a Swiss corporation; which in turn holds shares in Roche Holdings, Ltd., a Delaware corporation; which in turn holds shares in Hoffman-La Roche, Inc., a New Jersey corporation; which in turn holds shares in Roche Laboratories, Inc., a New Jersey corporation.

dispute that F. Hoffman does not own any shares in either of the U.S. Roche defendants and it, too, is a subsidiary of Roche Holding. The motion further left without dispute that the Swiss defendants do not have their own direct minimum contacts of the usual variety with California, i.e., no continuous or systematic business in or with the State such as would give rise to the exercise of general jurisdiction here, and they engaged in no acts constituting purposeful availment such that it would be fair and reasonable for a California court to exercise specific jurisdiction over either of them. The motion likewise established that although all the Roche entities are affiliated, each moving Swiss defendant was a distinct and separate company, with its own board and assets, and that each company maintained its own separate corporate records, bank accounts, and other financial and accounting books and records.

In their opposition to the motion, Wertheimers made no separation or distinction, evidentiary or otherwise, between or among any of the multiple Roche corporate entities, treating them all under the single moniker, “The Roche Group”—not a legal entity but a name used by the ultimate Swiss parent, Roche Holding, in certain consolidated financial and marketing reports. Nor did Wertheimers present any evidence of management or control of the domestic corporations by either of the Swiss defendants in terms of their day-to-day core business functions of the manufacture, production, sales, or distribution of pharmaceuticals, or in terms of the financial or accounting operations of either of the two U.S. Roche companies.

Wertheimers did present abundant evidence of integrated corporate activity among the Roche affiliated companies in one single arena—drug safety. This was reflected in the worldwide cooperation and collaboration among Roche pharmaceutical companies, regardless of domicile, in the gathering and study of drug adverse events reports, and in using these universally consolidated data for purposes of consistent drug labeling and reporting to various government drug regulatory agencies around the world, including the FDA in the United States.

In most instances, the evidence in this regard did not identify actions as having been performed by a particular Roche company. But it was established through the declaration of F.

Hoffman’s internal legal counsel that in the United States, it was Hoffman-La Roche, Inc., the New Jersey corporation, that was the “holder of the New Drug Application pursuant to which [that entity] sought and obtained approval for marketing Accutane™ from the United States Food and Drug Administration.” According to FDA regulations, then, it was this corporation, and not either of the Swiss Roche defendants, that was responsible and accountable for drug labeling and reporting issues in this country. (21 CFR § 310.305; 21 CFR § 314.80; see Dept. Health & Human Services, Food and Drug Administration, Guidance For Industry: Guideline for Postmarketing Reporting of Adverse Drug Experiences (Mar. 1992) pp. 2, 18.) Though it was clear that there was collaboration and integrated corporate involvement among the various Roche companies concerning regulatory and drug labeling issues and the collection of adverse event data, the Swiss defendants expressly denied either having labeled, or having controlled the labeling of, Accutane in the United States in the declarations filed in support of the motion.

On this record, the actual evidence concerning the degree of control over drug labeling and the entire adverse event data collection and reporting processes exercised by either of the Swiss Roche companies over the U.S. Roche defendants is largely undisputed. The parties nevertheless maintain opposing contentions about the characterization of this evidence or conclusions that may be drawn from it.<sup>4</sup> Wertheimers assert that the facts demonstrate control and domination over the U.S. Roche defendants by the Swiss defendants, who counter that the evidence shows only mutual collaboration in the isolated area of drug safety, and nothing more. The legal dispute that pivots on these facts is whether this single arena of Roche integrated corporate activity is enough to establish the U.S. Roche defendants as mere agents for purposes of jurisdiction, or to constitute them as just “incorporated departments” of the Swiss Roche conglomerate, or to show that either Swiss defendant exercised pervasive and

---

<sup>4</sup> We cannot help but charitably describe as overstatement many of Wertheimers’ characterizations or descriptions of the actual record, which, as petitioners note, reveals a disconnect between content and contention.

continuous control over either U.S. Roche defendant—all for purposes of applying the representative services doctrine as a species of agency.

What the evidence did establish is that since approximately 1995, all the Roche pharmaceutical companies worldwide have undertaken a collaborative effort to make uniform and global their processes for the collection, evaluation, and reporting of adverse drug side effects. This effort appears to have been designed to meet governmental drug regulatory and labeling requirements. It was directed and organized from outside the United States, though the U.S. Roche companies were themselves in control of and responsible for direct dealing with the FDA, including with respect to both drug labeling issues within the U.S. and the reporting of foreign adverse events as required by U.S. federal law. Roche entities in Basel, Switzerland had input on these issues as well, and the various entities acted cooperatively and collaboratively, but no particular Swiss Roche entity appears to have unilaterally directed or controlled the U.S. Roche companies on these discrete drug adverse event or labeling issues in a linear, chain-of-command sense, or beyond the establishment of general corporate policy. Instead, cooperation and collaborative decision-making best characterize the interplay among the various Roche companies concerning the global collection and reporting of adverse drug event data and related activities, even though the data were physically organized and analyzed in England and Roche executive corporate policies on these subjects did indeed emanate from Switzerland.

Wertheimers contended below, as they do here, that the facts concerning the collection of adverse event data and drug labeling and regulatory issues compel both a finding of agency and application of the representative services doctrine, such that jurisdiction can and should be exercised over both Swiss defendants on this basis. For this contention, they heavily rely on a Florida federal district court's unpublished orders in *Bishop v. Hoffman-La Roche, Inc., et al.*, (8:02-cv-1533-T-30TBM, Mar. 30, 2004) in which the court concluded that personal

jurisdiction over the Swiss entities could be exercised under Florida law based on agency.<sup>5</sup> Significant to that court were the Roche consolidated financial reporting and the collaborative drug regulatory compliance activities. But, according to the Swiss defendants, under Swiss law, Roche Holding is required “to establish a financial report for accounting purposes that consolidates the financial results of companies in which [it] owns a direct or indirect interest” and such reporting “does not affect the independence of the corporate entities” that are included within the report. Wertheimers did not rebut this evidence.

The trial court’s order denying the motion to quash here does not state its basis. The trial judge referenced the *Bishop* orders at the hearing, however, and stated that he was focusing on issues of “control” and relying on four specific items of evidence in exercising jurisdiction, all of which relate to the issue of agency and, ultimately, application of the

---

<sup>5</sup> There apparently are several similar cases pending around the country against the Roche companies arising from the prescribed use of Accutane. The record filed in this case includes orders from the *Bishop* case in Florida and from *Palazzolo, et al. v. Hoffman La Roche, Inc., et al.*, (ESX-5498-00, Jan. 19, 2002) [nonpub. opn.] in New Jersey. None of these orders has precedential or evidentiary value in this proceeding. (*People v. Crittenden* (1994) 9 Cal.4th 83, 120, fn. 3 [California courts “not bound by decisions of the lower federal courts, even on federal questions”].) And, their persuasive value is undercut by several factors.

First, in its initial order, the *Bishop* court denied several Swiss Roche defendants’ motion to dismiss under rule 12 (b)(6) of the Federal Rules of Civil Procedure for failure to state a claim. The motion included a challenge to personal jurisdiction that the court analyzed under Florida state law. The second *Bishop* order denied the Swiss defendants’ motion for reconsideration of the prior order. As discussed *post*, Florida law concerning the exercise of jurisdiction based on agency is distinguishable from California law.

Second, the New Jersey Superior Court’s order in *Palazzolo*, an action in which the Swiss companies were not even named as defendants, determined a discovery motion that touched upon the relationship among the U.S. and Swiss Roche entities. In its order, the court specifically said that it was not “definitively” deciding a jurisdictional question that was not before it.

Third, while these orders from trial-level courts may reflect a different conclusion regarding the propriety of the exercise of jurisdiction over the Swiss defendants by a court within the United States from that expressed here, it is not clear from the record in the case before us what the universe of evidence was before these other courts in Florida and New Jersey.

representative services doctrine. This cited evidence concerns just the one area of collaborative, corporate activity—the global collection, evaluation, and reporting of adverse event data and the generation of the “Core Data Sheet.” This document is the Roche medical and scientific policy, authority, and opinion that is formulated in Switzerland about a particular drug, and it is the primary information about the drug that goes into the labeling and drug reporting processes worldwide, subject to local corporate determinations and regulatory requirements.

### *Standard of Review*

When a nonresident defendant challenges personal jurisdiction, the plaintiff must prove, by a preponderance of the evidence, the factual basis that would justify the exercise of jurisdiction. (*Vons Companies, Inc. v. Seabest Foods, Inc.* (1996) 14 Cal.4th 434, 449 (*Vons*); *Pavlovich v. Superior Court* (2002) 29 Cal.4th 262, 273 (*Pavlovich*).) If the plaintiff meets this burden, it is then up to the defendant to show that the exercise of jurisdiction would be unreasonable. (*Ibid.*) In this analysis, the merits of the complaint are not implicated. (*Sonora Diamond Corp. v. Superior Court* (2000) 83 Cal.App.4th 523, 540 (*Sonora*).)

On review, the question of jurisdiction is, in essence, one of law. That said, when the facts giving rise to jurisdiction are conflicting, the trial court’s factual determinations are reviewed for substantial evidence. (*Sonora, supra*, 83 Cal.App.4th at p. 540.) Even then, we review independently the trial court’s conclusions as to the legal significance of the facts. (*Vons, supra*, 14 Cal.4th at p. 449; *VirtualMagic Asia, Inc. v. Fil-Cartoons, Inc.* (2002) 99 Cal.App.4th 228, 243-244 (*VirtualMagic*).) When the jurisdictional facts are not in dispute, whether the defendant is subject to personal jurisdiction is purely a legal question that we review de novo. (*Sonora, supra*, 83 Cal.App.4th at p. 540.) Thus, as both sides here acknowledge, the ultimate question whether jurisdiction is fair and reasonable under all the circumstances, based on the undisputed facts and those resolved by the court in favor of the prevailing party, is a legal determination warranting independent review. (*Vons, supra*, 14



Cal.4th at p. 449; *VirtualMagic, supra*, 99 Cal.App.4th at pp. 243-244; *Felix v. Bomoro Kommanditgesellschaft* (1987) 196 Cal.App.3d 106, 111.)

### *Analysis*

#### *1. Basic Principles of Jurisdiction*

California's long-arm statute permits a court to exercise personal jurisdiction over a nonresident defendant to the full extent permitted by the Due Process Clause of the United States Constitution. (Code Civ. Proc., § 410.10; *Pavlovich, supra*, 29 Cal.4th at p. 268.) Jurisdiction may be exercised on any basis not inconsistent with the federal or state Constitutions. (*Vons, supra*, 14 Cal.4th at p. 445.) In order to satisfy due process requirements, the defendant must have "minimum contacts" with the forum state such that the maintenance of the suit "does not offend the traditional notions of fair play and substantial justice." (*Internat. Shoe Co. v. Washington* (1945) 326 U.S. 310, 316; *Burger King Corp. v. Rudzewicz* (1985) 471 U.S. 462, 471-472 (*Burger King*); *Pavlovich, supra*, 29 Cal.4th at p. 268; *Vons, supra*, 14 Cal.4th at p. 445.) Minimum contacts exist where the defendant's conduct in the forum state is such that he should reasonably anticipate being subject to suit there, and it is reasonable and fair to force him to do so. (*World-Wide Volkswagen Corp. v. Woodson* (1980) 444 U.S. 286, 297 (*World-Wide Volkswagen*); *Kulko v. California Superior Court* (1978) 436 U.S. 84, 92 (*Kulko*); *Pavlovich, supra*, 29 Cal.4th at p. 269; *Vons, supra*, 14 Cal.4th at p. 445.) In contrast, contacts that are random, fortuitous, or attenuated do not rise to the minimum level, and general jurisdiction cannot be exercised under these circumstances. (*Burger King, supra*, 471 U.S. at p. 475; *Vons, supra*, 14 Cal.4th at p. 445.)

Pertinent here, we apply jurisdictional principles with an abundance of caution where the defendant is a foreign corporation. In this setting, "the question whether 'jurisdiction may be constitutionally exercised depends upon the circumstances of each individual case. . . . [T]he analysis is concerned with weighing the various relevant "contacts" by the foreign corporation within the state attempting to exercise jurisdiction.' (*Empire Steel Corp. v. Superior Court* (1961) 56 Cal.2d 823, 831.)" (*Sonora, supra*, 83 Cal.App.4th at p. 536.) But

in every case of an international defendant, the procedural and substantive interests of other nations in a state court's assertion of jurisdiction, as well as "the Federal interests in Government's foreign relations policies, will be best served by a careful inquiry into the reasonableness of the assertion of jurisdiction in the particular case, and an unwillingness to find the serious burdens on an alien defendant outweighed by minimal interests on the part of the plaintiff or the forum State. 'Great care and reserve should be exercised when extending our notions of personal jurisdiction into the international field.' *United States v. First National City Bank* (1965) 379 U.S. 378, 404 (Harlan, J., dissenting)." (*Asahi Metal Industry Co. v. Superior Court* (1987) 480 U.S. 102, 115 (*Asahi Metal*).)

The nature and the quality of the defendant's contacts determine whether jurisdiction, if exercised, is general or specific. General jurisdiction exists when a defendant is domiciled in the forum state or his activities there are substantial, continuous, and systematic. (*Helicopteros Nacionales de Colombia v. Hall* (1984) 466 U.S. 408, 414-416 (*Helicopteros*); *Vons, supra*, 14 Cal.4th at p. 445.) Factors leading to the conclusion that a defendant's contacts in the forum are continuous and systematic—none of which exist here with respect to the Swiss defendants—include maintenance of an office, presence of employees, use of bank accounts, and the marketing or selling of products in the forum state. (*Helicopteros, supra*, 466 U.S. at p. 415.) As the "minimum contacts" test is not susceptible of mechanical application (*Kulko, supra*, 436 U.S. at p. 92), these listed factors are not exhaustive but they provide guidance as to the type and degree of contacts the defendant must have in order to justify the exercise of general jurisdiction.

Even if a nonresident defendant's contacts with the forum state are not substantial, continuous, and systematic so as to support general jurisdiction, a court may still exercise specific or limited jurisdiction. This results where 1) the defendant has purposefully availed himself of the privilege of conducting activities in California, thereby invoking the benefits and protections of its laws; 2) the claim arises out of the defendant's California-related activity; and 3) the exercise of jurisdiction would be fair and reasonable and would comport with notions of

fair play and substantial justice. (*Helicopteros, supra*, 466 U.S. at pp. 414-415; *Vons, supra*, 14 Cal.4th at pp. 446-447; *Pavlovich, supra*, 29 Cal.4th at pp. 269-273; *Sonora, supra*, 83 Cal.App.4th at p. 536.)

Encompassed within the purview of general jurisdiction are the theories of alter ego and agency, of which the representative services doctrine is a species. (*Sonora, supra*, 83 Cal.App.4th at pp. 537-551.) Under these theories, the jurisdictional analysis bypasses the foreign defendant's direct "minimum contacts" with California as the contacts of that company are imputed via the presence of the local agent, through whom the foreign principal acts.

To invoke alter ego, two conditions must be met: 1) there must be such a unity of interest and ownership between the corporation and its equitable owner that the separate personalities of the corporation and the shareholder do not in reality exist; and 2) there must be an inequitable result if the acts in question are treated as those of the corporation alone. (*Sonora, supra*, 83 Cal.App.4th at p. 538; *Associated Vendors, Inc. v. Oakland Meat Co.* (1962) 210 Cal.App.2d 825, 837.)

The exercise of general jurisdiction through agency requires an analysis distinct from that of alter ego, though some of the factors are similar. (*Sonora, supra*, 83 Cal.App.4th at p. 540.) "In the case of alter ego, the court pierces the corporate veil. In the case of agency the corporate identity is preserved but the principal is held for the acts of the agent." (*Northern Natural Gas Co. of Omaha, Nebraska v. Superior Court* (1976) 64 Cal.App.3d 983, 994.) "An agency is proved by evidence that the [entity] for whom the work was performed had the right to control the activities of the alleged agent." (*Kim v. Sumitomo Bank* (1993) 17 Cal.App.4th 974, 983.) Thus, the hallmark of agency is the exercise of control over the agent by the principal.

But for purposes of jurisdiction, the analysis begins with the "firm proposition that neither ownership nor control of a subsidiary corporation by a foreign parent corporation, without more, subjects the parent to the jurisdiction of the state where the subsidiary does business." (*Sonora, supra*, 83 Cal.App.4th at p. 540.) " 'Control' in this context means the

degree of direction and oversight normal and expected from the status of ownership; it comprehends such common characteristics as interlocking directors and officers, consolidated reporting, and shared professional services. [Citations.] The relationship of owner to owned contemplates a close financial connection between parent and subsidiary and a certain degree of direction and management exercised by the former over the latter. [Citations.]” (*Sonora, supra*, at pp. 540-541.)

Thus, for purposes of acquiring jurisdiction over the foreign parent company based on agency, that company must exercise a degree of control over the local entity that is more pervasive than these common features signal. It must veer into management by the exercise of control over the internal affairs of the subsidiary and the determination of how the company will be operated on a day-to-day basis. (*Sammons Enterprises, Inc. v. Superior Court* (1988) 205 Cal.App.3d 1427, 1434 (*Sammons*); *Williams v. Canon, Inc.* (C.D. Cal. 1977) 432 F.Supp. 376, 380.) It is the “rare occasion” where a court is willing to treat a parent and subsidiary as one entity for jurisdictional purposes. (*Calvert v. Huckins* (E.D. Cal. 1995) 875 F.Supp. 674, 678.) In the absence of a showing of fraud or injustice, courts will generally respect the presumption of corporate separateness in a jurisdictional analysis. (*Ibid.*; *Sammons, supra*, 205 Cal.App.3d at p. 1434.)

The law does identify one situation where the acts of the parent cross the line of legitimate ownership and control of the subsidiary, exposing the parent to the jurisdiction of the state in which the subsidiary does business. This circumstance is when the nature and extent of control exercised over the subsidiary is “so pervasive and continual” that the subsidiary is but the agent or instrumentality of the parent even though separate corporate formalities are maintained. (*Sonora, supra*, 83 Cal.App.4th at p. 541.) The control exercised must be “over and above that to be expected as an incident of the parent’s ownership of the subsidiary and must reflect the parent’s purposeful disregard of the subsidiary’s independent corporate existence.” (*Id.* at p. 542; *DVI, Inc. v. Superior Court* (2002) 104 Cal.App.4th 1080, 1087, 1093-1094.) General executive control is insufficient. Rather, “there must be a strong

showing beyond simply facts evidencing ‘the broad oversight typically indicated by [the] common ownership and common directorship’ present in the normal parent-subsidary relationship. [Citations.] As a practical matter, the parent must be shown to have moved beyond the establishment of general policy and direction for the subsidiary and in effect taken over performance of the subsidiary’s *day-to-day* operations in carrying out that policy. [Citations.]” (*Sonora, supra*, 83 Cal.App.4th at p. 542.) Mere “ownership of a locally incorporated subsidiary does not warrant the exercise of jurisdiction over a foreign corporation unless the foreign parent ‘manipulates the subsidiary to the detriment of creditors or the subsidiary is the alter ego of the parent. (*Empire Steel Corp.* [, *supra*, 56 Cal.2d at p. 831] [citations omitted].’ (*Westinghouse Electric Corp. v. Superior Court* (1976) 17 Cal.3d 259, 274.)” (*J. M. Sahlein Music Co. v. Nippon Gakki Co., Ltd.* (1987) 197 Cal.App.3d 539, 543.)

Under the representative services doctrine, as a species of agency, general jurisdiction may be exercised over a related foreign defendant principal, where the local entity as agent essentially exists only to further the business of the foreign entity, and but for the domestic entity’s existence, the foreign entity would be performing those functions in the forum itself. (*Sonora, supra*, 83 Cal.App.4th at pp. 540-546.) The doctrine supports jurisdiction “when the local subsidiary performs a function that is compatible with, and assists the parent in the pursuit of, the parent’s *own* business . . . .” (*Sonora, supra*, 83 Cal.App.4th at p. 543.)

In contrast, jurisdiction will not lie where the parent is a true holding company the business of which is not operations but passive investment. (*Sonora, supra*, 83 Cal.App.4th at p. 543.) In this setting, application of the doctrine is limited to the circumstance in which the parent uses a subsidiary to do what it otherwise would do itself in the operational sense. (*Ibid.*) The doctrine has been applied not only in the parent/subsidiary context, but also where the two companies are separately owned affiliates, and the local company nevertheless performs functions in furtherance of the foreign company’s, as opposed to its own, business. (*Paneno v. Centres For Academic Programmes Abroad Ltd.* (2004) 118 Cal.App.4th 1447, 1456.)

2. *The Exercise of Jurisdiction Over Either Swiss Defendant Based on the Forum  
Contacts of the U.S. Roche Defendants Was Error*

As to neither Swiss defendant, F. Hoffman or Roche Holding, was there substantial, indeed any, evidence of its own direct minimum contacts or purposeful availment of the forum such that the exercise of jurisdiction, whether general or specific, by a California court was proper.

The only theory seriously posited by Wertheimers for the exercise of jurisdiction over either Swiss defendant was agency via application of the representative services doctrine.<sup>6</sup> They urge that the Swiss entities have minimum contacts with the State of California through the acts of the U.S. Roche defendants, who Wertheimers assert, are their agents. But the record here does not establish agency with respect to either Swiss defendant, as evidence of the requisite level of pervasive and continual control that defines the principal/agent relationship for purposes of jurisdiction under California law is lacking as to each of them. (*Sonora, supra*, 83 Cal.App.4th at p. 541; *Cislaw v. Southland Corp.* (1992) 4 Cal.App.4th 1284, 1292-1296.)

---

<sup>6</sup> Even though Wertheimers also contend that the U.S. Roche entities are the alter egos of the Swiss defendants, as they did below, they have not pleaded alter ego allegations and their return cites no evidence in the record to support jurisdiction on this basis. As discussed *ante*, there are two requirements for an alter ego finding: (1) that there is such a unity of interest and ownership between the corporation and its equitable owner that, in reality, their separateness does not exist; and (2) treatment of the acts in question as those of the corporation alone would lead to an inequitable result. (*Associated Vendors, Inc. v. Oakland Meat Co., supra*, 210 Cal.App.2d at p. 837.) These requirements are demonstrated by analysis of an oft-cited set of factors, all of which Wertheimers identify but none of which they analyze here with reference to evidence in the record. (*Ibid.*; *Sonora, supra*, 83 Cal.App.4th at pp. 538-539.) While under the appropriate set of facts, application of the alter ego doctrine may support the exercise of jurisdiction (*Sonora, supra*, 83 Cal.App.4th pp. 537-538.), under these circumstances where there are no citations to the record to support the argument, we will treat the alter ego theory of jurisdiction as having been waived. (*Nwosu v. Uba* (2004) 122 Cal.App.4th 1229, 1246 [reviewing court not required to search the record on its own seeking error]; *City of Lincoln v. Barringer* (2002) 102 Cal.App.4th 1211, 1239 [record citations in “factual background” portion of brief do not cure failure to include pertinent record citations in argument].) And, having reviewed the record, we do not on our own locate substantial evidence to support an alter ego finding in any event.

In fact, with respect to the day-to-day operations of the U.S. Roche defendants—in terms of management of the manufacture, sales, and distribution of pharmaceutical or chemical products, or the associated auditing or financial aspects of this business—there was a void of evidence of control exerted by either Swiss defendant. Indeed, there was nothing to suggest that either Swiss defendant was even involved in these managerial operations or that the U.S. Roche defendants did not actually function as independent entities. The facts instead showed the opposite, with no more than a bilateral, collaborative involvement or corporate integration by the U.S. Roche defendants with the Swiss Roche affiliates in the discrete area of drug safety. Even here, the degree of control over the processes exercised by any Swiss entity was not pervasive or continual, and it did not exceed that ordinary and necessary degree of control incident to ownership of a subsidiary or rise to the point of purposeful disregard of the subsidiary’s independent existence. (*Sonora, supra*, 83 Cal.App.4th at pp. 541-542.)

Pharmaceutical companies worldwide operate within governmental regulatory schemes for the benefit and protection of the public health and welfare. In the U.S., drug companies are required by FDA regulations to report “spontaneous adverse events occurring within the United States” and to report on “[f]oreign, literature, and study reports involving: [¶] . . . [s]erious, unlabeled events [and] [¶] . . . [i]ncreased frequency of serious, labeled events.” (Dept. Health & Human Services, Food and Drug Administration, Guidance For Industry: Guideline for Postmarketing Reporting of Adverse Drug Experiences (Mar. 1992) pp. 1-2.) “Reports of serious, unlabeled events must be reported to [the] FDA . . . as soon as possible, but in any case within 15 working days of the time of initial receipt of the information by the applicant.” (*Id.* at p. 2) These reporting obligations that govern the U.S. Roche defendants thus extend beyond the United States and require these companies to “establish effective mechanisms to ensure rapid information transfer from their foreign affiliates.” (*Id.* at p. 4.) In fact, according to FDA regulations, the U.S. Roche defendants—as the sponsors of Accutane in the U.S.—were themselves required to be responsible to, and to deal directly with, the FDA

concerning these reporting issues relating to Accutane in this country. (21 CFR § 310.305; 21 CFR § 314.80.)

In order to meet these requirements, the U.S. Roche defendants, in cooperation with other Roche-affiliated entities worldwide, established a global and centralized drug safety reporting system “to ensure optimal compliance with a strong ethical commitment and today’s regulatory requirements.” (Alan L. Bess, MD, *A Successful Global Drug Safety System: The Hoffman-La Roche Experience*, Drug Information Journal, Vol. 33 (1999) at p. 1112.) The Roche activities related to the system of drug labeling and regulatory processes were indeed organized in Switzerland. The generation of the Roche Core Data Sheet for a particular drug, including Accutane, was also directed out of Basel, and the non-Swiss Roche affiliates were not authorized to generate an independent medical opinion that was inconsistent with that contained in this document. But it was undisputed that the U.S. Roche affiliates collaborated in the development of the Core data sheet, which was just the minimum scientific information to be published about a particular drug. It was also undisputed that each Roche affiliate had the ability to modify this information to comply with local drug labeling and reporting requirements, and that the U.S. Roche entities had some authoritative say if there was disagreement over these issues, subject only to deference to general, executive policy over these matters that originated from outside the United States.

Apart from the collection of adverse event drug data and related labeling and regulatory issues, there was evidence of consolidated financial reports of all the Roche entities, which, according to F. Hoffman and Holding Co., are required of parent companies under Swiss law. But the U.S. Roche entities still maintained their own separate financial and accounting books and records. There was also evidence of some consolidated media releases that addressed activities of various Roche entities without distinction or separation between or among them. But under California law, consolidated reporting, joint employment of professional services, and the use of “we” or “the company” are typical and actually expected of affiliated or wholly owned companies, and such facts do not establish agency for purposes of jurisdiction.



(*Sonora*, *supra*, 83 Cal.App.4th at pp. 540-541, 550; *DVI*, *supra*, 104 Cal.App.4th at p. 1096 [consolidated 10-K SEC reporting insufficient for jurisdiction].) The evidence here of joint reporting or collective media releases did not go beyond this normal incidence of ownership that is contemplated within the parent/subsidiary context. Accordingly, this evidence does not subject the Swiss defendants to the exercise of jurisdiction. (*Ibid.*)

Fundamentally, then, Wertheimers presented no evidence of control over the U.S. Roche companies by either Swiss defendant in terms of management of their core, day-to-day operations—the manufacture, distribution, and sales of pharmaceuticals—or the financial or accounting aspects of these drug operations. And, in terms of the exercise of control by any Swiss Roche entity over the U.S. Roche entities in any respect, there was only the evidence of cooperation and collaborated implementation by the U.S. Roche entities of Roche global company policies and procedures concerning drug safety that emanated from Roche Switzerland.

Thus, the question presented distills down to this: Was the degree to which either of the Swiss Roche defendants “managed” the global collecting, study, or reporting of adverse drug events and corresponding labeling and regulatory issues—the only aspect of any modicum of control exercised—sufficient to establish the U.S. Roche defendants as agents or instrumentalities of either Swiss company such that the exercise of general jurisdiction over either F. Hoffman or Roche Holding by a California court is proper? This question must be addressed separately as to each of these defendants. On this record, as to each, we answer this question in the negative. This conclusion is compelled by the record here and in that sense, it is a product of the respective burdens of proof that the parties bore in the trial court on the motion to quash.

With respect to Roche Holding, there was no evidence that this entity is, or conducts itself as, anything other than a true passive holding company that globally invests in pharmaceutical subsidiaries, including the two U.S. Roche defendants here, with no exercise of operational control whatsoever over these subsidiaries. Ownership or control of a subsidiary

by a parent corporation, without more, is insufficient to subject the parent to jurisdiction in the state where the subsidiary does business. (*Cannon Mfg. Co. v. Cudahy Co.* (1925) 267 U.S. 333, 336; *Sonora, supra*, 83 Cal.App.4th at pp. 540-541.) Where, as here, the evidence establishes that the business of the foreign holding company is mere passive investment, the exercise of jurisdiction based on a theory of agency is wholly improper. (*Sonora, supra*, 83 Cal.App.4th at p. 543.) Thus, the trial court erred with respect to its exercise of jurisdiction over Roche Holding because Wertheimers did not meet their burden of proving that this entity is other than a passive parent holding company, which merely invests in pharmaceutical subsidiaries and exercises the normal and expected incidents of ownership such as the setting of general and executive corporate policy.

The trial court likewise erred by the exercise of jurisdiction over F. Hoffman. While this entity is not a holding company and thus cannot defeat jurisdiction on the same basis as its parent, Roche Holding, the record does not contain substantial evidence to justify the exercise of jurisdiction over it by a California court as a matter of law. This conclusion holds true under general principles of agency, as well as under the representative services doctrine.

In other words, the record does not establish either that F. Hoffman exercised pervasive and continuous control over the business of either of the U.S. Roche defendants so as to establish a general agency relationship, or that the U.S. entities acted as mere instrumentalities of F. Hoffman in the furtherance of *its* business to invoke jurisdiction under the representative services doctrine. (*Sonora, supra*, 83 Cal.App.4th at pp. 540-546; *Paneno, supra*, 118 Cal.App.4th at pp. 1455-1457; *DVI, Inc., supra*, 104 Cal.App.4th at pp. 1092-1097.) Agency was not established for the simple reason that there was no evidence of pervasive and continuous operational control of either of the U.S. Roche defendants by F. Hoffman. And, although the collaborative functions of this Swiss entity and those of the U.S. Roche defendants relating to the collection, evaluation, and reporting of drug adverse events reports overlapped, and general policy and direction about these activities emanated from Switzerland, there is no evidence in this record from which we could conclude that the degree to which this

occurs extends beyond broad oversight indicated or warranted by common affiliation or ownership and into operational control. (*Sonora, supra*, 83 Cal.App.4th at pp. 542-543.)

It likewise appears that the operational activities of neither U.S. Roche defendant were in furtherance of F. Hoffman's business, but rather each of them advanced its *own* pharmaceutical business, thus precluding the exercise of jurisdiction by application of the representative services doctrine. (*Sonora, supra*, 83 Cal.App.4th at pp. 540-546; *DVI, supra*, 104 Cal.App.4th at 1087-1097.) The facts in this regard are distinct from those in *Paneno, supra*, 118 Cal.App.4th 1447, on which Wertheimers principally rely.

The plaintiff in *Paneno*, a student who had contracted with a California affiliate of a British company for education abroad services, was severely injured on the premises of his leased residence in Italy. It was the English company that actually administered the programs and had entered into contracts with local entities in the home countries to house the foreign students. The California affiliate, though not a subsidiary, was an "administrative arm" of the British company. As such, it performed marketing and recruiting of students, and actually entered into the contracts with them and the educational institutions within California for the provision of international study programs, all in furtherance and as an extension of the British company's business. (*Paneno, supra*, 118 Cal.App.4th at pp. 1451-1452.) While the students would pay their money to the California company, it would in turn transmit the funds directly to the British company. (*Ibid.*)

In affirming the exercise of general jurisdiction over the British company, the Court of Appeal emphasized that unlike the parent company in *Sonora, supra*, the foreign entity in *Paneno* was not just a holding company but was itself engaged in business operations closely connected to the domestic entity, which performed functions solely to assist the British entity in *its* business. (*Paneno, supra*, 118 Cal.App.4th at pp. 1456-1457.) The court also emphasized that the two companies had specifically designed their operating structure by trickery—with one company to recruit students and the other to provide accommodations abroad—all to avoid having to answer for claims in California. (*Id.* at p. 1457.)

Simply put, we have no evidence of either of these factors here. With respect to Roche Holding, it is a true holding company, and there is nothing to suggest that the U.S. Roche defendants conduct their core pharmaceutical operations—manufacturing, distribution, sales, accounting, and finance—other than autonomously or that they do so simply in furtherance of Swiss Roche business. This is so despite the single sphere of global and collaborative Roche drug regulatory compliance and safety activities, which alone are insufficient to establish general agency or control exerted over the U.S. Roche defendants by either Swiss Roche defendant. Neither can it be inferred from the evidence in this record that the global Roche corporate structure is designed or conducted through trickery or deception. And the *Paneno* court’s concern with forcing the plaintiff there to sue abroad is irrelevant here where the two U.S. Roche defendants remain answerable in damages to plaintiffs’ claims within California.

What is more, the Swiss defendants’ efforts to distinguish California from Florida law as applied by the federal district court in the *Bishop* case are persuasive. First, in Florida there appears to be a different burden-shifting mechanism on a motion to quash that is less favorable to a defendant at the outset. For example, there the allegations of the complaint are accepted as true and the plaintiff need not prove up jurisdictional facts with evidence until after a defendant meets his burden to challenge jurisdiction. (*Future Technology Today v. OSF Healthcare Systems* (11th Cir. 2000) 218 F.3d 1247, 1249 (per curiam); *Doe v. Thompson* (Fla. 1993) 620 So.2d 1004, 1005; *Acquadro v. Bergeron* (Fla. 2003) 851 So.2d 665, 671, citing *Venetian Salami Co. v. Parthenais* (Fla. 1989) 554 So.2d 499, 502.) Second, Florida’s long-arm statute specifically provides for jurisdiction based on agency, and the degree of control exercised by the foreign principal must be shown to be “very significant” as opposed to the more burdensome “pervasive and continuous” degree that California law requires. (Fla. Stats. § 48.193, subd. (1); *State v. American Tobacco Co.* (Fla.App.4th Dist. 1998) 707 So.2d 851, 854-855; *Pappalardo v. Richfield Hospitality Services, Inc.* (Fla.App.4th Dist. 2001) 790 So.2d 1226, 1228 [“significant dominion or control” by parent corporation sufficient to establish jurisdiction through agency]; cf. *Sonora, supra*, 83 Cal.App.4th at p. 542; *DVI, Inc., supra*, 104

Cal.App.4th at pp. 1087, 1093-1094.) Third, in Florida, at least as pertinent to the district court in *Bishop*, consolidated financial reporting and shared professional services appear to be indicative of agency as opposed to the normal integration of companies that share common ownership, as such facts are characterized by California law. (*Sonora, supra*, 83 Cal.App.4th at pp. 540-541; *DVI, supra*, 104 Cal.App.4th at p. 1096.)

Finally, we agree with the Swiss defendants that the exercise of jurisdiction on the sole basis of their collaborative and global efforts “to create a more efficient, more responsive and ultimately safer system for monitoring and reporting adverse events associated with prescription drugs worldwide” would be unreasonable. A determination of the reasonableness of the exercise of jurisdiction in a given case involves evaluation of several factors: the burden on the defendant, the interests of the forum state, and the plaintiff’s interest in obtaining relief. (*Asahi Metal, supra*, 480 U.S. 102, 113.) A court must also weigh “ ‘the interstate judicial system’s interest in obtaining the most efficient resolution of controversies; and the shared interest of the several States in furthering fundamental substantive social policies.’ [(*World-Wide Volkswagen, supra*, 444 U.S. at p. 292.)]” (*Asahi Metal, supra*, 480 U.S. at p. 113.) Where an international defendant is concerned, a court must also “consider the procedural and substantive policies of other *nations* whose interests are affected by the assertion of jurisdiction by the California court.” (*Asahi Metal, supra*, 480 U.S. at p. 115.)

Here, a holding that jurisdiction over the Swiss defendants should be exercised due solely to their global, collaborative drug safety efforts would ultimately discourage such laudable and very topical efforts by pharmaceutical companies and lead to the balkanization of drug safety data, thereby reducing their completeness, accuracy, and consistency, and the speed and efficacy with which the data becomes available to drug regulators around the world. There are sound policy reasons for the encouragement, rather than penalization, of worldwide, coordinated efforts by global drug companies to gather and report as much accurate information as possible concerning drug safety. This activity alone should not result in a court’s exercise of jurisdiction over a foreign parent or affiliated pharmaceutical company, so

long as the foreign company does not otherwise establish minimum contacts with California or purposefully avail itself of this forum, and the domestic pharmaceutical subsidiaries or affiliates, like the U.S. Roche defendants here, do not cede true operational control of their businesses to foreign parent or affiliated companies, thereby exposing them to the exercise of jurisdiction within the state. Given the scrutiny being applied today to the safety of prescription drugs and the FDA processes that allow them to come to market, we are persuaded by the worthiness of this consideration. Moreover, in this case, it bears repeating that Wertheimers are not left without a remedy; there is no jurisdictional barrier to the pursuit of their claims against the U.S. Roche defendants, and no hint in this record that these domestic companies are incapable of responding in damages in the event of an adverse result.

*Disposition*

For the above reasons, the trial court's exercise of general jurisdiction over both Swiss defendants F. Hoffman and Roche Holding was error in that it offends constitutional due process considerations. Let a peremptory writ of mandate issue commanding the trial court to vacate its July 15, 2004 order denying the motion of F. Hoffman and Roche Holding to quash service of summons and enter a new order granting the motion. The stay of the action as to the petitioners previously issued by this court is hereby dissolved. Petitioners are awarded their costs incurred in this original proceeding.

---

Walsh, J.\*

---

\*Judge of the Santa Clara County Superior Court assigned by the Chief Justice pursuant to article VI, section 6 of the California Constitution.

WE CONCUR:

---

Premo, J.

---

Elia, J.

Trial Court:

Santa Clara County  
Superior Court No. CV006507

Trial Judge:

Hon. Kevin E. McKenney

Attorneys for  
Petitioners:

Daniel J. Herling  
Lina M. Brenner  
DUANE MORRIS

Frederick D. Baker  
SEDGWICK, DETERT, MORAN & ARNOLD

No appearance for  
Respondent

Attorney for Real  
Parties In Interest:

Ara Jabaghourian  
Frank Pitre  
COTCHETT, PITRE, SIMON & MCCARTHY

Michael Ryan  
KRUPNICK, CAMPBELL, MALONE

F. Hoffman-La Roche, Ltd. et al. v. Superior Court (Wertheimer)  
H027794